

REMARKS/ARGUMENTS

Applicants wish to thank the Examiner for the telephone interview for this application.

Support for the Amendments

The amendments to Claims 1, 27, and 28 to recite that an aqueous dispersion of drug particles is formed can be found in those claims as originally filed. The amendment to remove the term "at or" in claims 1, 27, and 28 is for the purpose of clarifying the invention, as is the amendment to make claim 26 dependent from claim 19.

The 103 Rejections

The Examiner rejected Claims 1 and 4-28 under 35 USC 103(a) as being unpatentable over US Patent 5,985,248 to Gordon. Submitted herewith is a declaration of Keith P. Johnston setting forth the differences between the present invention and Gordon. As described in the declaration and in the amended claims, the present invention is directed to a method for preparing an aqueous dispersion of poorly water soluble drug compounds. The method includes, in part, a step of spraying a drug/organic mixture via an atomizing device into an aqueous solution, wherein the drug/organic mixture is sprayed below the liquid level of the aqueous solution. By contrast, Gordon teaches spraying in air, thereby forming a dry powder and not an aqueous dispersion.

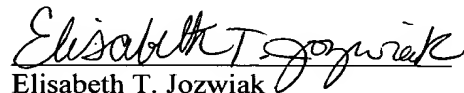
Applicants would also like to note that the declaration submitted herewith describes the importance of spraying below the liquid level in the method of the present invention. That is, by spraying below the liquid level using the method of the present invention, water is present together with the drug particles. The water solvates stabilizers that are present with the drug particles, thereby giving the stabilizers a desirable orientation on the drug surface, such that the stabilizers cover the growing drug particles and inhibit growth. By contrast, water is not present using the method taught by Gordon.

For these reasons, Claims 1 and 4-28 are not obvious in view of Gordon.

CONCLUSION

Based on the foregoing amendments and remarks, Applicants believe the present application is in condition for allowance. Early notification thereof is respectfully requested. As agreed during our telephone interview, the Examiner will call the attorney at the phone number listed below if there are any remaining outstanding issues.

Respectfully submitted,


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ETJ/ab



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Appl. No. : 09/808,332 Confirmation No. 3850
Applicant (s) : Keith P. Johnston, et al.
Filed : March 14, 2001
TC/A.U. : 1615
Examiner : Amy E. Pulliam
Title : PREPARATION OF DRUG PARTICLES USING EVAPORATION
PRECIPITATION INTO AQUEOUS SOLUTIONS

Docket No. : 61112
Customer No. : 00109

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November 12, 2003

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION

I, Keith P. Johnston, declare and state:

THAT I am a Professor of Chemical Engineering at the University of Texas in Austin, Texas, and that I am an inventor named on the above identified patent application;

THAT I am aware that the above-identified application is a United States Patent application filed on March 14, 2001, which claims the benefit of provisional application, U.S. Serial No. 60/245,479, filed November 3, 2000;

THAT I am aware that the present application had an Official Action mailed June 12, 2003, which I have read along with the cited references, including that of Gordon et al. [U.S. Patent No. 5,985,248], and that, pursuant to telephone communications with the Examiner on October 22, 2003, the Examiner would like to see arguments, made in declaration form, describing the differences between the invention claimed in the present application with the teachings of Gordon;

THAT, to overcome the rejections raised, the following remarks are submitted;

THAT, I am aware that the above-identified application, in claims 1 and 28, claims a method for preparing an aqueous dispersion of poorly water soluble drug particles, and that this method comprises, in part, spraying a drug/organic mixture below the surface of an aqueous solution;

THAT, I am aware that Gordon does not teach preparing an aqueous dispersion, but rather, Gordon teaches producing a dry powder by spray drying into a vapor phase;

THAT, I am aware that the orientation of stabilizer on the drug particles is highly dependent upon the media surrounding the drug particles;

THAT, in the present application, the medium surrounding the drug particles is water, and that most of the water surrounding the drug particles does not evaporate;

THAT, in the spray drying method taught by Gordon, the medium surrounding the drug particles is vapor, due to the fact that a solvent mixture of an organic solvent and water is sprayed to evaporate both the organic solvent and water to produce a dry powder, and that there is very little water left behind;

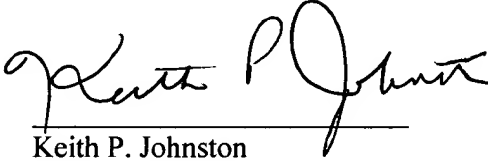
THAT, in the present application, at the end of the particle formation process, the particles are dispersed in an aqueous solution, that the water that is present will solvate the stabilizers, giving the stabilizers a desirable orientation on the drug surface such that the stabilizers cover the growing drug particles and inhibit growth;

THAT, in the spray drying method taught by Gordon, there is no water left behind to solvate the stabilizers, and that, as a result, growth of the drug particles is not likely to be inhibited by the stabilizer and the particle size is typically relatively large.

The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment,

or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date 10-31-03


Keith P. Johnston

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ETJ/ab